process for preparing the inventive TTS. The inventive TTS exhibits improved processing and delivery properties (see Example I and Example 2).

It is believed that no fee is required for the consideration of this Amendment. If it is determined that a fee is due, the Assistant Commissioner is authorized to charge such fee, or credit any overpayment to Deposit Account 50-0320.

This Amendment cancels all the pending claims in favor of new claims 7 to 14. Support for this new set of claims is found in the claims which they replace. As this new set of claims does not narrow the scope of the patent protection originally sought and serves to overcome formal matters, the application of the doctrine of equivalence is not affected.

The specification was objected to for not containing an abstract or a brief description of the drawings. An abstract is enclosed and a paragraph, which provides a brief description of the drawings, was inserted into the specification. Thus, the withdrawal of this objection is requested.

Claim 6 stands rejected under 35 U.S.C. § 101 for being nonstatutory and claims 2 to 5 stand rejected under 35 U.S.C. § 112, second paragraph, for being indefinite for formal reasons. It is urged that the new set of claims makes these rejections moot and the withdrawal of this rejection is requested.

Claims 1 to 5 stand rejected for allegedly being unpatentable over Hoffman, U.S. 5,820,876 taken in view of Von Kleinsorgen, Canadian Patent 2,250,025 ("Kleinsorgen") and in further view of Anhäuse et al., Canadian Patent 1,336,368 ("Anhäuse"). As none of these prior patents taken in any fair combination suggests a TTS which comprises an active agent depot or a matrix that comprises a support material which consists of paper, it is urged that the rejection

does not establish a *prima facie* case of obviousness and reconsideration and withdrawal of the rejection are requested.

The rejection acknowledges that Hoffman does not disclose a TTS wherein the active agent depot or the matrix comprises a support material which is paper. Office Action at 4. In order to correct the deficiency, the rejection relies upon Kleinsorgen alleging that this patent "teaches that paper is used as the substrate for the system during the production process, though it does not share all of the structural components of the claimed invention." *Id.* The rejection relies upon Anhäuse to teach that it "is known in the art of transdermal pad production that the process permits an accurate dosage with a variance of $\pm$2%." *Id.* Hence, the rejection does not rely on the disclosure of Anhäuse to teach an active agent depot or a matrix that comprises a support material which is paper. The rejection then concludes

> one of ordinary skill in the art would have been motivated to combine the substrate of Von Kleinsorgen with the structural system of Hoffmann in order to provide a lighter weight, cheaper TTS with improved active agent diffusion. It would have been obvious to one of ordinary skill in the art, at the time of the invention to combine these teachings along with knowledge in the art with the expected result of a TTS with easier diffusion properties.

Applicants respectfully disagree since Kleinsorgen discloses the use of paper as a substrate on which a separation layer is applied which does not suggest using paper in a active agent depot or matrix.

This present invention provides for a TTS in which the active agent depot or the matrix comprises paper as a support material. As discussed on pages 1 to 3, the prior art does not teach using paper for this purpose and the prior materials used as support material are fundamentally different from paper (see especially page 2, line 19 *et seq.*). Moreover, the use of

paper as a support material for these components has distinct advantages over the prior material, such as fabrics. Examples 1 and 2 demonstrate some of these advantages.

Hoffman provides for a conventional TTS. As discussed on page 2, line 25 *et seq.*, the depot and the matrix components do not contain paper. The support materials disclosed in Hoffman, which distribute the active substance within the fabric, are a planar fabrics such as a nonwoven fabric such as cotton (see col. 3, lines 10 to 19; col. 7, line 18 to 20). Thus, not only is Hoffman "silent" with respect to the inclusion of paper for these components, the patent teaches away from the use of paper since paper has properties which are different from fabrics (see page 2, third paragraph of the specification).

Kleinsorgen does not correct this deficiency. From the claims, from Fig. 1 to 3 and the explanation of the figures on page 14, and from the discussion on page 5, lines 3 to 8, it is clear that the paper layer used in the TTS according to this patent application serves as a substrate on which a separating layer is applied (page 5, lines 3 and 4), the latter of which may be a water-soluble substance; e.g. a saccharide or polysaccharide, a polyhydroxy alcohol, PVP, polyethylenglycole or gelatine, or a fat-soluble substance, e.g. a triglyceride or a wax (page 7, lines 11-16). The second purpose of the paper is that it serves as a substrate for a printing process according to the screen printing method (page 12, lines 25-28) where, for example, the system name can be printed on the substrate (page 12, lines 31 to page 13, line 1+2). It follows from Figures 1 to 4 and the manufacturing example of that the paper substrate is always the outer-most layer. Hence, it is not used as a support layer in a depot or matrix material and Kleinsorgen does not provide any motivation to include paper in these components.

Further, Applicants respectfully disagree that one of ordinary skill in the art would have been motivated to combine the substrate of Von Kleinsorgen with structural system of Hoffmann in

order to provide a TTS having be advantages disclosed in the present specification. This combination would provide for a TTS wherein the backing layer of Hoffmann would consist of paper on which a separating layer comprising water-soluble or fat-soluble substances might be applied. Since neither the paper layer nor the combination of paper layer with the separating layer would possess the required properties of the backing layer according to Hoffmann, i.e. impermeability for the active substances, one skilled in the art would not be motivated to make this substitution. As previously noted Anhäuse does not correct this deficiency. Moreover, while Anhäuse discloses that it is known in the art of transdermal pad production that the process permits an accurate dosage with a variance of $\pm 2\%$, the substrates discussed therein consist of rubber-elastic materials such as natural and synthetic rubbers (page 4, first para.) and not to a paper substrates.

Thus, in view of the foregoing it is urged that the rejection does not establish a *prima facie* case of obviousness and the withdrawal of this rejection is requested.

Favorable action is earnestly solicited.

Respectfully submitted,

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